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SCHLUMBOHM ELECTRONIC

EndoPilot®

Operating Manual

EndoSystem for root canal preparation, modular and multi-functional: **EndoMotor** with integrated **Apexlocator,** also **Downpack-** and **Backfill-module**

CE 0482

609 2201 v03

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1. Symbols

Symbol:	Description:
CE 0482	The product complies with the requirements of the EC Directive 93/42
	Particular protection against electric shock
	Warning: Consult the User Manual If the instructions are not being followed properly, operation may result in damages of the product or in hazards for the user or patient.
	This medical device falls under the WEEE Directive (Directive 2002/96/EEC) concerning waste of electrical and electronic equipment. Do not dispose this type of waste with the normal garbage. Follow the national regulations in force.
	single use only
	contains Guttapercha
	contains Silver
	shelf-time
	European Representive
	Please read! Additional information, explanation of operation and performance.

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2. General precautions

Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and the fact, that the use is not being able to foresee the possibilities of accidents.
For your safety please read this instruction carefully and completely.
Prior to the first usage ensure that you and your staff are familiar with the operation of this device.
If questions or problems arise please stop usage and contact the supplier.

2.1 General warnings and conditions for operation

- Prior to installation, check the device for damages.
- Do not install the device in damp places or in places where it will come into contact with liquids.
- Do not expose the unit to direct or indirect sources of heat.
- The EndoPilot has been designed for dental use only and should be operated by specialized physicians licensed to practise dentistry.
- Do not use the device for anything else than its intended purpose.
- Do not alter or modify the product in any way, Schlumbohm declines any and all responsibility in case of alteration or modification of the device.
- Follow the manufacturer's instructions for use and disposal of the endodontic files.
- The accuracy of the length determination, the torque and rotation speed can only be ensured if the *EndoPilot 1:1 contra-angle* is used.
- Accurate canal measurement is not always possible, especially in case of abnormal or unusual canal morphology (for example blocked or fractured canals).
- The torque and speed tolerance is 10%
- Never use other power supplies than the permitted medical-power-supply that has been delivered with the device.
- Do not use the device in the presence of free oxygen or flammable gases or fluids.
- The Guttapercha contains natural rubber, which may cause an allergic reaction. (latex cross-allergy).
- Never use the EndoPilot close to other devices which are emitting electromagnetic radiation. The electromagnetic interference may leed to a variation during length determination.

Contra-Indication:

- Never use the EndoPilot in patients with pacemaker.
- The use of GuttaPercha in patients with a known sensitivity to latex, silver or copper may cause an allergic reaction. Such an allergic reaction to latex may result in swollen eyes, lips or face. It may also cause difficulty in breathing. The patient should be advised to notify you immediately if any of these symptoms occur.

2.2 Intended usage

The EndoPilot is designed to be used exclusively in dental practice.
Do not connect the system to any other device.
This EndoSystem is exclusively made for:

- mechanical root-canal cleaning with rotating NiTi Files,
  this function can be used with integrated length determination
- thermal filling of root-canals with guttapercha.
- chemical caries removal with Carisolv®
- cleaning and polishing teeth during prophylaxis

3. Getting started

3.1 Installation

First, please check the delivered components and the shipping-documents. Now compare the serial- and LOT-numbers with the numbers on the components.

Please note! All components are delivered unsterile!

During installation, pay attention on following aspects:

- the space for the stand must be horizontal
- do not expose the unit to direct sunbeams
- the ambient temperature should be in the range 15 °C- 40°C
- do not install the device in the presence of oxygen, flammable gases or liquids.
- do not install the device close to devices which are emitting strong electromagnetic radiation.

3.2 Connection

The „Push and Pull“ connectors for the handpieces and the foot switch are colour coded.

Red:	Backfill handpiece (B-Fill button)
Black:	foot switch
Blue:	1. Motor or 2. D-Pack handpiece for obturation
Green:	Apexcable, connection to the patient (lip-clip)

The power supply has to be connected to the foot switch.

All connectors are push and pull connectors, do not turn the connectors during plugging.

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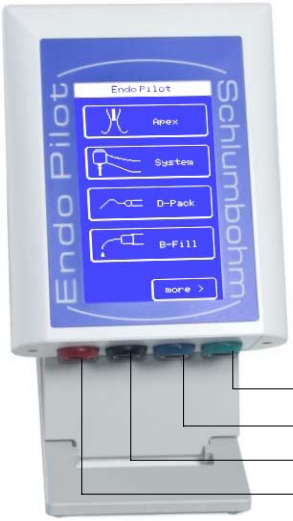


apex cable
motor / D-Pack
foot switch
Backfill hand-piece

standard tripod nut

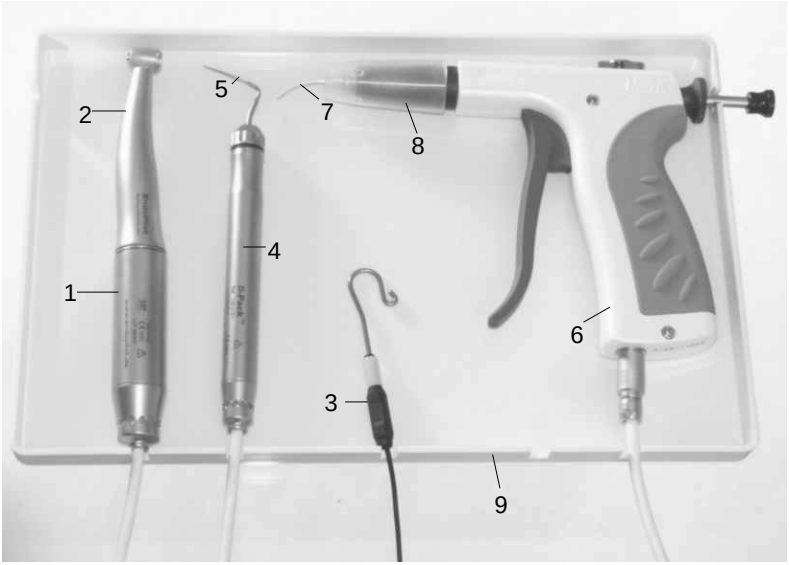
tripod-screw

Connect the Control-Box to the stand by using the tripod-screw.

There are many other ways to mount or arrange the device
(for example with a photo tripod)

3.3 Tray for hand-pieces

A tray keeps the hand-pieces in place.
(this tray isolates the hand-pieces from possible external leakage-voltage)



1	109 0112	**EDP-motor** with ISO-E-fitting, LED-light indicator and integrated Apex-contact
2	109 0121	**EDP-hand-piece**, 1:1, isolated, with ISO-E-fitting
3	109 2311	**Apex-cable** with Lip-clip
4	109 0151	**Down-Pack hand-piece**, with LED-light indicator
5	109 0153	**Pen tip** size: fine
6	109 0141	**Back-Fill hand-piece**
7	109 0144	**Needle** size: # 20gauge
8	109 0143	**heat cover**
9	109 2302	**Tray** for hand-pieces, white (included, depending on configuration)

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3.4 Touch-Display

All functions of the EndoPilot could be activated with the big, comfortable touch-display. The touch-display allows an intuitive and self-explanatory handling.
The display is operated directly by a soft touch of the finger tip. Certainly it is possible to use gloves. As an alternative a pen with a plastic-tip can be used.

Never use parts from metal!

With the Back-Key you will always return to the last screen.

3.5 Foot Control

The foot-switch is used for the following functions:

- Start/Stop of the motor
- Saving the measured root length (see chapter 4.0)
- Start/Stop of the D-Pack heating-process
- Reactivating the EndoPilot from sleep-mode

3.6 Switch-on, standby mode, switch-off

The EndoPilot is activated by plugging the foot-control (the black connector), power-supply and foot-control must be connected first.

After a while of inactivity the device will switch to sleep-mode. Sleep mode shuts of the display-light. If work should be continued, a short step on the foot-switch will activate the unit again. The EndoPilot returns to the last screen.

If the EndoPilot is not used for a longer period of time, it is highly recommended to disconnect the power-supply from the mains, that will save the energy consumption of the sleep-mode.

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3.7 Motor and contra-angle

The EndoPilot contra-angle is placed on the ISO-fitting of the motor. Only use contra-angles with 1:1 gear.

The integrated apex-length-measurement with contra-angle ("on the fly") is only available with the original EndoPilot contra-angle.

If the contra-angle has been changed, it is necessary to run the calibration-procedure, for that choose the menu "option".

remarks about operating:

Endo: The Endo files are bent and stressed during the usage, depending on the shape of the root-canal. Although the risk of instrument fracture is reduced by the EndoPilot it cannot be eliminated completely. Please make sure that you know the allowed torque limit. Never use files which are elongated or damaged.

Pay attention to the points listed below to avoid a file-breakage:

- Never use excessive force to insert the file or to move the file forward.
- Nickel-titanium files will eventually break due to metal fatigue; do not use the same file to treat more canals than the file-manufacturer allows.
- It takes some practice and experience to learn to use nickel-titanium files effectively. Therefore it's recommended, that the dentist practices on extracted teeth or root canal plastic-models.

Prophylaxis: There are several tool-sets from different manufacturers available. Select the right speed- and torque, follow the instructions of the tool-manufacturer. Please make sure, that the gear-head of the contra-angle is kept free from polishing-paste.

Carisolv: The tips for Carisolv™-treatment, are specially designed. They are designed to work in both directions; clockwise and anticlockwise. When rotating clockwise (red mode), the cutting edges are more aggressive than if the tip rotates anticlockwise (green mode). In this mode the instruments have blunt edges. These characteristics of the tips, coupled with the fact that the processor in the control unit measures the used torque, helps the dentist to dissolve the caries efficiently and to remove it with gentle scraping (at the surface of the dentine.)

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LED Motor:

- Green: Torque below 80% of selected torque-setting
- Red: Torque above 80% of selected torque-setting

3.8 D-Pack

The D-Pack hand-piece is connected to the blue socket of the control box (also the motor uses this socket).

The chuck of the hand-piece can be opened by unscrewing the nut (two turns are enough). Now the Pen-tip can be inserted. The tip is clamped by tightening the nut.

Always check if the tip is fixed before you start working.

If it is impossible to unscrew the nut by hand, please use the tool (see below).

LED D-Pack:

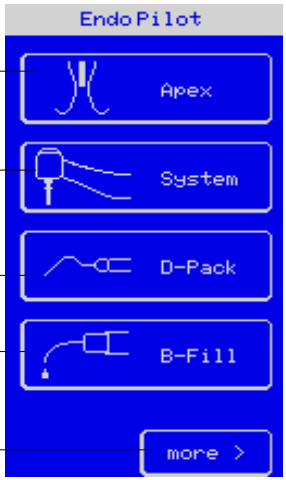
- Red, blinking: D-Pack is operating, heating procedure is running

3.9 Backfill

Connect the BackFill hand-piece with the delivered cable. Screw on a new needle, fix it with the tool (6). Please, always use a heat cover (5) to prevent burns. Press the locking knob (2) and pull the piston (1) backwards. Now insert one pellet of guttapercha into the slot of the hand-piece (only one pellet at the time). By pressing the trigger (3), you will push the guttapercha into the heating chamber and later into the needle. If the handpiece is worm you have to load up fast to prevent the inner parts from blocking. As long as the selected temperature has not been reached, you should not press to hard, otherwise you could damage the gun. If you put the handpiece aside, make sure that the surrounding surfaces are heat resistant.

1 piston
2 locking knob
3 trigger
4 needle
5 heat cover
6 tool

Functions overlook-menu I



4.0 Manual root canal measurement

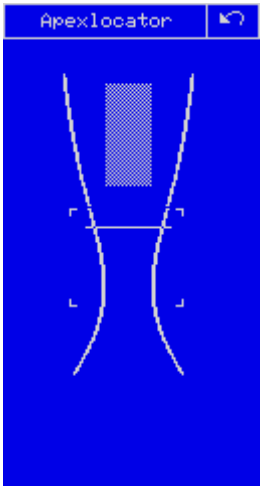
5.0 Motor system for NiTi files

6.0 DownPack-Module

7.0 BackFill-Module

. next menu

4.0 Manual root canal measurement



With this menu you can measure manually, that means with an hand driven file (for example for a first probing). The separate file clip and the lip clip are used for this function.

The horizontal line shows the position in the root canal where the "auto-stop"-function in the motor menu is reached. The setting can be done by pushing the line directly on the touch-display or can be comfortably stored by pressing the foot-switch. The adjustment is kept till the shut-off. After a shut-off the limit will return back to the standard setting.

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1 apex-cable
2 file clip
3 lip clip

4.1 Tips for an accurate measurement

Put the lip clip on the lip of the patient (in the corner of the mouth, on the opposite side you are working on). Before you start the length determination, the root canal should be rinsed with NaCl solution and then dried with a cotton-pellet to prevent mistakes during measurement, generated by leakage current. It is recommended to wear gloves during measurement in order to isolate the measuring current. Connect the file clip to the file (below the shaft) and insert the file carefully into the root canal.

The results of the length determination always should be compared with an x-ray image.

5.0 Motorsystem

5.1 file system

5.2 sequence / file

If you select the menu motorsystem you will get to the last file system you have been working with. The layout principle of the screen for all different systems is always the same but there are differences in the structure and the sequences depending on the file system or the manufacturer.

5.1 Selection of file-system and MyFile (Hybrid-Technique)

You can choose between the listed systems just by a short touch. With the "back" key you will return to the last selected System.

With the *"MyFile"* function you have a special option to create own comprehensive mix-sequences (Hybrid-Technique). The *"MyFile"* function can be activated directly at all file-systems.

5.2 Selection of a sequence or file

After selecting a file system you can choose a file or sequence. When the file has been selected, the *"f.data" key appears.*

With this key or menu you can change the specific values of the selected file individually.

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5.3 File parameters

Twist-Function

File starts anticlockwise

Safes this file in the MyFile-Sequence

Speed-value of the file

Torque-value of the file

Wear-value of the file in the used box (menu options)

Defined limit for the file-alarm

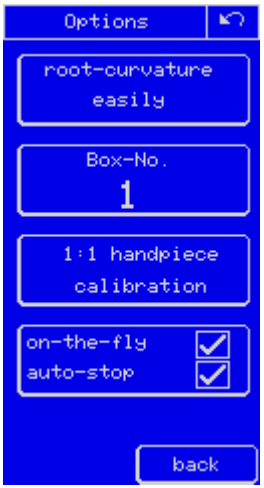
After *"RPM", "Ncm" or "Box"* has been selected you can adjust the values by pressing the "**+**" and "**-**" keys on the screen. The keys *"RPM", "Ncm"* between the "**+**" and "**-**" button sets the values back to the settings which the manufacturer recommends. In the menu-function "factory settings" it is also possible to reset the values of all files at once.

5.4 Options

The settings which applies for the whole preparation can be adjusted in the menu "*options*". These settings are: The selection of the "root-canal-shape", it acts as a factor for the wear-monitoring and the selection of the file-box.

After a box has been selected (1 to 6), all wear-values of the different files, which are used during the preparation are booked on the account of this box.

The function "contra-angle calibration", should be activated if the contra-angle has been changed.



5.5 *"on the fly"*

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5.5 Apexlocator, usage with motor "on-the-fly"

One of the main functions of the EndoPilot is the root canal measurement during canal preparation. The remarks from chapter 4 apply principally also to this function but with the addition, that the function of the file clip is replaced by the contra-angle. The isolated contra-angle leads the measuring signal to the file. The lip clip is still necessary to close the circuit. Always take an x-ray to confirm the results.

Overall there are 3 operating modes available:

A. "on-the-fly" with "auto stop"

While the motor is activated by pressing the foot switch, the apex menu opens up, input or changes are impossible. The selected file and the selected values will be displayed.

If the horizontal line (which might has been adjusted during manual measurement) is reached, the motor stops for 2 seconds. A tone-signal and flashing red LED´-light indicates that the torque limit will be reduced ("torque reduction") from now on. The patented torque-reduction, close to the apex, reduces the cutting force at the tool and helps to bring out the dentine-chips continuously.

B. "on-the-fly"

While the motor is activated by pressing the foot switch, the apex menu opens up, input or changes are impossible. The selected file and the selected values will be displayed.

If the horizontal line (which might has been adjusted during manual measurement) is reached, a tone-signal indicates the position. The motor does not stop and the torque limit is not reduced.

C. "on-the-fly" off

While the motor is activated by pressing the foot switch, the menu for file-selection is displayed. The root canal measurement is inactivated.

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6. Down-Pack

If the D-Pack module is connected, you can choose the temperature of the pen-tip just by a short touch. The heating process can be started directly by pressing the foot switch. If the foot switch is released or after 30 seconds the heating process ends.

With the B-Fill-key you will jump directly to the Backfill-menu.

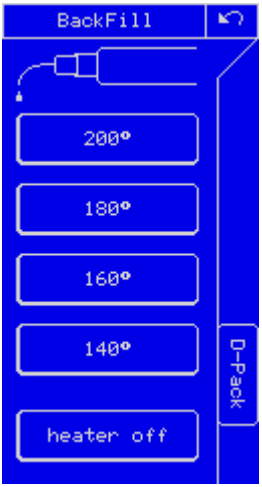
Please see also chapter 3.8

7. Backfill

If the BackFill module is connected, you can choose the temperature inside the heating-cylinder of the gun just by a short touch. The heating process is started after the temperature has been selected. After approximately 6-10 minutes the heating process ends (tone-signal). The heating-process can be shut off by pressing the „heating off“-button.

With the D-Pack-key, you will jump directly to the DownPack-menu.

Please see also chapter 3.9



Functions overlook-menu II

8.0 *Carisolv*

9.0 *Prophylaxis*

10.0 Factory Settings (reset)

11.0 *Setup*

. *back to the last menu*

8. Carisolv®

In the Carisolv® menu you can choose between two different programs (depending on the different tools)

Please see chapter 3.7

Motor LED's:

green: anticlockwise

red: clockwise

Further information you will get from:

MediTeam AB

Medicinaregatan 8 B, 5th Floor

SE-413 46 Göteborg

Sweden

www.mediteam.com

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9. Prophylaxis

In the Prophylaxis-menu you can choose between different speed / torque settings.

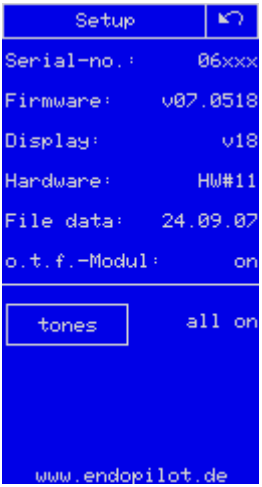
Please see also chapter 3.7

The EndoPilot monitors the needed torque continuously. The motor stops automatically if the torque limit is reached. The motor starts again when the needed torque is reduced.

10. Return to the Factory Settings

This function sets all individual file-parameters and MyFile settings back to the factory settings.

11. Setup, updates and tone-signals



In the Setup menue you can see the hard- and software information of your device.

Especially for service and updates it is helpful or necessary to have these information.

With the menue behind the "*tones*"-button you can adjust the audible tones of the device individually.

12. Cleaning, disinfection, sterilisation (processing of resterilisable medical devices)

Further information you will find in the attached instructions:

1. processing of resterilisable medical devices / Instruction Part I

   The unit in general with tray, contra-angle and motor

2. processing of resterilisable medical devices / Instruction Part II

   Apex-cable, D-Pack und BackFill module

13. Maintenance

Information about maintenance you will also find in the attached instructions (please see chapter 12.)

Please check the cables and connectors at least every 5 month

Attention !

- Do not lubricate the motor for any reason.
- If the contra-angle is cleaned or lubricated (in accordance to the instruction above), please make sure that no lubrication or cleaning liquids will enter the motor.

The EndoPilot contains no parts that can be repaired at the clinic. If the device is opened or if it is modified the warranty will be expired (please read chapter warranty). Service must be done by the manufacturer.

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14. Warranty and liability

S c h l u m b o h m® warrants the control-box against defects in material or workmanship for a period of one year from date of original invoice. S c h l u m b o h m®`s sole obligation under product warranty is (at its sole discretion) to repair or replace any defective component or product in part or whole. S c h l u m b o h m® shall be the sole arbiter of such action.

In the event of an alleged defect under warranty, the purchaser must inform the Schlumbohm Customer Service immediately. The Customer Service will provide instructions, usually directing that the product be returned in its entirety for service. Shipment to S c h l u m b o h m® and the cost thereof is always the responsibility of the purchaser.

Accidental misuse or inappropriate use voids the warranty.
S c h l u m b o h m® does not warrant for wear and dirt in the hand-pieces, modules or contra-angles.

S c h l u m b o h m® does not assume any risk or liabilities arising from the clinical use of its products, whether or not such use involves coincidental utilization of medical devices (pacemaker etc.) manufactured by others.

15. Technical specifications

Technical changes reserved

Type:	EndoPilot
Electric Supply	Input: 90-264V/AC Output: 12V/1,25 A /DC according to IEC601 (power cord for medical devices)
Electrical safety class	class II
Output	max. 3V/5A or.12V/1,25A (DC)
Operation	Device designed for short-term use
Speed	200-1000 rpm +/- 10%
Torque	0,2 -5 Ncm +/- 10%
Device class	EN 60601-1, Type BF
IP class:	Permeation protection for control-box and foot-switch IP52
MPG / EU class	IIa
Environment conditions	15° C - 40°C / RH: 20-80%

16. Manufacturer's data

for further information please contact us at any time:

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